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Information Exchange System

Alert No. 109

Virologic failure in HIV patients treated with the combination of Didanosine, Lamivudine and Tenofovir

The European Medicines Evaluation Agency (EMA) has issued a public statement warning about the high rate of virologic failure in HIV patients treated with a triple nucleoside/nucleotide reverse transcriptase inhibitors combination containing didanosine, lamivudine and tenofovir. The statement is based on the observations from a clinical study of HIV-infected treatment-naïve patients receiving a once-daily triple combination containing tenofovir (Viread[®], TDF), lamivudine (Epivir[®], 3TC) and didanosine enteric coated beadlets (Videx[®] EC, ddI EC). The precise nature of any interaction leading to non-response is currently unknown and will be investigated further. In the meantime,

- physicians are advised not to start treatment-naïve or treatment-experienced HIV patients on a new therapeutic regimen containing tenofovir in combination with didanosine and lamivudine;
- patients already on therapy with the above combination should be frequently monitored with a sensitive viral load test (limit of quantification <50 copies/ml) and considered for modification of therapy at the first sign of viral load increase;
- patients currently using the above combination regimen should inform their doctor immediately.

The public will be updated with conclusions from the assessment of additional information from the marketing authorization holder and from other relevant ongoing studies as soon as they are available.

A similar public statement was issued by the EMA in July 2003 for a different triple nucleosides/nucleotide combination containing abacavir, lamivudine and tenofovir (Ref. EMA/20194/03).

Reference:

EMA Public Statement, EMA/CPMP/5094/03, 22 Oct 2003.